#### **REMARKS**

This responds to the Office Action dated April 26, 2007. Claims 1, 10, 13, 14, 16, 19, 23, 24, 27, 28, 30, 32, 41, 44, 45, 47, 50, 54, 58, 59, 61, and 63 are amended. Claims 8, 9, 39, 40, and 149 are canceled. Claims 150 and 151 are added. Claims 1-7, 10-38, 41-148, and 150-151 are now pending in this application.

Applicant respectfully requests clarification on the Examiner's request at page 2 of the Office Action to point out particular references in the IDS which they believe may be of particular relevance to the instant claimed invention. Specifically, the Examiner is requested to clarify what is a reference of "particular relevance".

#### The Nonstatutory Obviousness-Type Double Patenting Rejection

Claims 1-3, 8-13, 32-34, 39-44, 63-78, and 149 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-109 of copending U.S. application Serial No. 10/890,825. Claims 1-3, 8-10, 13, 32-34, 39-41, 71-75, and 149 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 13 and 15-18 of copending U.S. application Serial No. 11/220,397. Claims 1-3, 8-9, 13, 32-34, 39-40, 44, 63-64, 71-75 and 149 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 11-13 and 16-17 of copending U.S. application Serial No. 11/276,077.

Applicant notes that U.S. application Serial Nos. 10/890,825, 11/220,397 and 11/276,077 have not yet issued and are pending. Therefore, a terminal disclaimer is not required in these matters until issuance of one of them. If a terminal disclaimer is required in any of Serial Nos. 10/890,825, 11/220,397 and 11/276,077, it can be requested by the Office before issuance of those matters.

# The 35 U.S.C. § 103 Rejection of the Claims using Soykan and Levine

Claims 1-2, 8, 13, 32-33, 39, 44, 63, 65-67, 71-73, and 149 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soykan et al. (U.S. published application No. 2001/0000802) in view of Levine et al. (U.S. published application No. 2002/0019350).

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As amended, claim 1 includes elements originally recited in claim 9 (now canceled), and claim 32 includes elements originally recited in claim 40 (now canceled).

Applicant is unable to find in Soykan et al. and Levine et al., among other things, a teaching or suggestion of an event detector adapted to detect a predetermined cardiac condition from a sensed physiological signal and produce one or more condition parameters related to at least one of a type and a degree of the predetermined cardiac condition, and a controller adapted to quantitatively control the emission of the regulatory signal based on the one or more condition parameters, as recited in claims 1 and 32.

The Office Action states, in paragraph 20:

The previously modified Soykan reference discloses the claimed invention as discussed above except the detector 57 is not specified to comprise an event parameter generator to produce one or more condition parameters related to at least one of a type and a degree of the predetermined cardiac condition and the controller 92 is not specified to comprise a regulatory signal parameter controller to quantitatively control the emission of the regulatory signal based on the one or more condition parameters.

Thus, it is admitted in the Office Action that Soykan et al. and Levine et al., in combination, do not provide the event detector and the controller as recited in claims 1 and 32.

The obviousness rejection of claims 9 and 40 as applied to the amended claims 1 and 32 is addressed below, under "The 35 U.S.C. § 103 Rejection of the Claims using Soykan, Levine and Darvish".

Claims 2, 8, and 13 are dependent on claim 1 and are believed to be patentable at least for the reasons supporting patentability of claim 1 as discussed above. Claims 33, 39, 44, 63, 65-67, and 71-73 are dependent on claim 32 and are believed to be patentable at least for the reasons supporting patentability of claim 32 as discussed above.

Applicant respectfully requests reconsideration and allowance of claims 1-2, 8, 13, 32-33, 39, 44, 63, 65-67, and 71-73.

# The 35 U.S.C. § 103 Rejection of the Claims using Soykan, Levine and Hamm

Claims 3 and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soykan et al. in view of Levine et al. as applied to claims 1 and 32 above, and further in view of Hamm et al. (U.S. published application No. 2004/0030379).

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Applicant respectfully traverses the rejection. Claim 3 depends on claim 1, and claim 34 depends on claim 32. Thus, the discussion above for claims 1 and 32 is incorporated herein to support the patentability of claims 3 and 34.

Applicant respectfully requests reconsideration and allowance of claims 3 and 34.

# The 35 U.S.C. § 103 Rejection of the Claims using Soykan, Levine and Darvish

Claims 9 and 40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soykan et al. in view of Levine et al. as applied to claims 1, 8, 32 and 39 above, and further in view of Darvish et al. (U.S. published application No. 2002/0183686).

Claims 9 and 40 have been canceled. However, as amended, claim 1 includes elements of claim 9, and claim 32 includes elements of claim 40. Therefore, the rejection of claims 9 and 40 as applied to the amended claims 1 and 32 are hereby addressed.

Applicant respectfully traverses the rejection. The discussion above for claims 1 and 32 is incorporated herein to support the patentability of claims 1 and 32 as amended herein, over the combination of Soykan et al., Levine et al. and Darvish et al.

The Office Action states, in paragraph 20, that "Darvish further discloses that the device is used to control the type, timing and/or dosage of molecule to be applied (see Darvish Abstract, page 1, paragraphs 7-10, page 2, paragraphs 16 and 18-19 and page 3, paragraphs 22-30). However, with respect to the regulatory signal, the Office Action states, in paragraph 6: "The controller 92 is also electrically wired to gene regulatory delivery device (i.e. the coil of antenna lead 24) via antenna lead 24, which emits a regulatory signal (i.e. an RF signal) for indirectly effecting gene transfer/expression (see Soykan Fig. 2-1 and 5 and page 10, paragraph 88). Darvish et al. relates to "release of a molecule" but not an RF signal that is considered to be the regulatory signal in the Office Action. Therefore, Applicant respectfully submits that the proposed modification and combination of references do not result in a controller adapted to quantitatively control the emission of the regulatory signal based on the one or more condition parameters, as recited in claims 1 and 32.

Additionally, Applicant respectfully submits that the proposed modification and combination of the references are improper. The Office Action states that "it would have been obvious to one having ordinary skill in the art at the time the invention was made ... to modify

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the controller of Soykan in view of Darvish to comprise a regulatory signal parameter controller to quantitatively control the emission of the regulatory signal based on the one or more condition parameters to allow the application regimen to be varied in response to needs of the excitatory tissue." As asserted in the Office Action, the RF signal of Soykan et al. reads on the regulatory signal recited in claims 1 and 32. Applicant respectfully submits that one having ordinary skill in the art would not modify the controller of Soykan et al. by using the device of Darvish et al., which "is used to control the type, timing and/or dosage of molecule to be applied", to quantitatively control the emission of the RF signal of Soykan et al.

Applicant respectfully requests reconsideration and allowance of claims 1 and 32.

# The 35 U.S.C. § 103 Rejection of the Claims using Soykan, Levine and Donahue

Claims 10-12 and 41-43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soykan et al. in view of Levine et al. as applied to claims 1, 8, 32 and 39 above, and further in view of Donahue et al. (U.S. published application No. 2002/0155101).

Applicant respectfully traverses the rejection. Claims 10-12 ultimately depend on claim 1 and claims 41-43 ultimately depend on claim 32. Thus, the discussion above for claims 1 and 32 is incorporated herein to support the patentability of claims 10-12 and 41-43.

Applicant respectfully requests reconsideration and allowance of claims 10-12 and 41-43.

#### The 35 U.S.C. § 103 Rejection of the Claims using Soykan, Levine and Donahue

Claims 64 and 68 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soykan et al. in view of Levine et al. as applied to claims 32, 63 and 67 above, and further in view of Shelton et al. (U.S. Patent No. 5,312,453).

Applicant respectfully traverses the rejection. Claims 64 and 68 ultimately depend on claim 32. Therefore, the discussion above for claim 32 is incorporated herein to support the patentability of claims 64 and 68.

Applicant respectfully requests reconsideration and allowance of claims 64 and 68.

#### The 35 U.S.C. § 103 Rejection of the Claims using Soykan, Levine and Brady

Claims 69-70 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soykan et al. in view of Levine et al. as applied to claims 32, 63 and 67 above, and further in view of Bardy (U.S. Patent No. 5,314,430).

Applicant respectfully traverses the rejection. Claims 69-70 ultimately depend on claim 32. Therefore, the discussion above for claim 32 is incorporated herein to support the patentability of claims 69-70.

Applicant respectfully requests reconsideration and allowance of claims 69-70.

### The 35 U.S.C. § 103 Rejection of the Claims using Soykan, Levine and Nelson

Claims 74-78 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soykan et al. in view of Levine et al. as applied to claim 32 above, and further in view of Nelson et al. (U.S. published application No. 2002/0072785).

Applicant respectfully traverses the rejection. Claims 74-78 ultimately depend on claim 32. Therefore, the discussion above for claim 32 is incorporated herein to support the patentability of claims 74-78.

Applicant respectfully requests reconsideration and allowance of claims 74-78.

#### New Claims

New claims 150 and 151 have been added. Applicant believes that no new matter is added and that the new claims are appropriate for consideration in the present application.

Applicant respectfully requests consideration and allowance of claims 150 and 151.

Filing Date: February 27, 2004

Title: METHOD AND APPARATUS FOR DEVICE CONTROLLED GENE EXPRESSION

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# **CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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<u>CERTIFICATE UNDER 37 CFR 1.8:</u> The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450,

Alexendria, yA 22313-1450 on this 26 day of September 2007.

Name

Signature